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Bureau of Health Professions Licensure
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MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Best Practice Recommendations for Controlled Substance Inventory Management

The Massachusetts Board of Pharmacy (Board) has adopted these Best Practice Recommendations in order to promote optimal controlled substance inventory management in the Commonwealth.

These recommendations can be applied in all different pharmacy settings and include a variety of measures, some of which can be implemented immediately and others that can be instituted over time. This is **not** an all-inclusive list, but serves as supplemental suggestions to the licensees' existing policies and procedures.

The Board strongly urges all pharmacies to consider these recommendations and implement those measures suitable to their particular practice. The Board believes that adoption of these practices will result in the timely detection of discrepancies or losses, reduce the likelihood of theft, as well as increase personal accountability, patient safety, and enhance medication delivery systems.

According to Board inspectional data, in 2016, investigators discovered numerous violations relating to controlled substance recordkeeping upon inspection. Listed below for review are the most common controlled substance inspectional deficiencies cited by investigators.

A. Perpetual Inventory

1. Observed discrepancies in the perpetual inventory log in violation of 247 CMR 9.01 (1) and 21 CFR 1304.21 (d).
    a. Perpetual inventory had missing and/or inaccurate entries in violation of 247 CMR 9.01 (14).
    b. Expired schedule II medications were not inventoried in violation of 247 CMR 9.01 (14).

B. Biennial Inventory

1. Biennial inventory not available at the time of inspection, in violation of 247 CMR 6.07 (1) (b), 247 CMR 6.07 (1) (i), 247 CMR 9.01 (1) and 21 CFR 1304.11(a)).
2. Biennial inventory not completed biennially, in violation of 247 CMR 9.01(1) and 21 CFR 1304.11(a).

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Best Practice Recommendations for Controlled Substance Inventory Management

1. **Conduct your Biennial Inventory with exact counts on all controlled substance medications.**
   a. An exact count inventory reduces the likelihood of an unknown loss as a result of an inaccurate estimated count.
   b. An established exact count inventory provides pharmacies with an accurate starting point for reconciliation in the event of a theft or loss of a controlled substance.
   c. Conduct an exact count controlled substance inventory annually. Annual inventories reduce the elapsed time between exact counts, to have a more accurate picture of your inventory.

2. **Develop policies and procedures relating to the storage and documentation of expired/damaged/recalled controlled substances.**
   a. Expired / damaged / recalled controlled substances should be stored in a secure location.
   b. Maintain a log and conduct regular inventory.
   c. Ensure these controlled substances are reverse distributed in a timely manner to reduce likelihood of losses, theft, or the re-dispensing a medication which had previously been dispensed.

3. **Develop policies and procedures to increase staff accountability and awareness of proper controlled substance inventory management.**
   a. Review dispensing and ordering history for frequently out of stock products at your pharmacy. This practice may result in early detection/ reduction of a controlled substance theft or loss.
   b. Pharmacies should have a reliable method for determining the expected quantity on hand for controlled substances.
   c. Develop a procedure for performing a reconciliation of controlled substances based on the product movement history (ordering, dispensing, etc.).
   d. Develop a policy for increased random inventory counts of controlled substances. Frequent and random checks of controlled substances assist with the timely detection of discrepancies or losses as well as deter theft.
   e. Develop a policy for conducting a “back count” of controlled substance medications during the prescription filling process. Conducting “back counts” of controlled substances assist with reduction of loss as a result of operational errors.

4. **Develop policies and procedures to create a record of accountability that can be retrieved, reviewed or acted upon at a future date.**
   a. Develop an internal program where controlled substances practices are checked. Review records for accurate completion of inventory related tasks (e.g. order receiving procedures, perpetual inventory records, prescription logs, etc.). Maintain a log of the results of the review. Awareness of random compliance checks increases accountability for pharmacy personnel.

b. Utilize the results of the internal monitoring program to uncover and change unsafe practices and correct repetitive faults and identify staff members who may benefit from additional training on the management of controlled substances.
c. Results from the internal monitoring program may assist implement procedure improvements and/or in editing or updating current policies and procedures.

5. Develop policies and procedures to ensure the security of controlled substances.

a. Designate a location for employees' personal items (bags, backpacks, coats, jackets, etc.) outside of the prescription processing and storage area. Consider using lockers or a break room.
b. Develop a policy for performing random end-of shift bag / smock checks.
c. Develop a policy limiting access to the pharmacy to designated authorized individuals. The policy should include the supervision of non-designated individuals (vendors, maintenance, etc.) as needed.

6. Ensure pharmacy staff is familiar with Board of Pharmacy Policy 16-02: Requirements and procedures for reporting theft or loss of controlled substances to the Board of Registration in Pharmacy.

a. For any suspected and/or confirmed controlled substance loss, pharmacies shall, as outlined in Policy 16-02:

    1. Conduct a thorough investigation.
    2. Adhere to the timely reporting requirements.
    3. Follow reporting procedures.
    4. Submit required documentation.

Controlled Substances Management Review
SITE VISIT REPORT

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Professions Licensure

Board of Registration in Pharmacy
239 Causeway Street, Suite 500, 5th Floor, Boston, MA 02114
(617) 973-0800
(617) 973-0988 TTY

DATE(S) OF SITE VISIT:		INSPECTION #: ISP-
PHARMACY DBA NAME:		
STORE NUMBER:		
STREET ADDRESS:		
CITY / STATE / ZIP:		
TELEPHONE:		
FAX:		
EMAIL:		
PHARMACY LIC. NUMBERS:		
PHARMACY LIC. EXPIRATION:		
MANAGER OF RECORD (MOR):		
DAILY PHARMACY VOLUME:	□ LESS THAN 100	
	□ 100 TO 500	
	□ ABOVE 500	
CONDITIONS ON LICENSE AS A RESULT OF A LOSS OF CONTROLLED SUBSTANCES? Y N (Circle Y or N)	If yes- describe conditions:	DISCIPLINARY SANCTIONS FOR DRUG LOSSES (e.g.-Reprimand)? If yes, list below:
NUMBER OF REPORTABLE LOSSES IN THE PAST 24 MONTHS #	List losses below (include loss type and date):	

PHARMACY STAFFING			
PHARMACY STAFF PRESENT AT TIME OF SITE VISIT			
PHARMACISTS	LICENSE #		CURRENT?
1			□ YES □ NO
2			□ YES □ NO
3			□ YES □ NO
4			□ YES □ NO
5			□ YES □ NO
6			□ YES □ NO
PHARMACY INTERNS	LICENSE #		CURRENT?
1			□ YES □ NO
2			□ YES □ NO
3			□ YES □ NO
PHARMACY TECHNICIANS	CERTIFIED?	LICENSE #	CURRENT?
1	□ YES □ NO		□ YES □ NO
2	□ YES □ NO		□ YES □ NO
3	□ YES □ NO		□ YES □ NO
4	□ YES □ NO		□ YES □ NO
5	□ YES □ NO		□ YES □ NO
6	□ YES □ NO		□ YES □ NO
7	□ YES □ NO		□ YES □ NO
8	□ YES □ NO		□ YES □ NO
9	□ YES □ NO		□ YES □ NO
10	□ YES □ NO		□ YES □ NO
OTHER PHARMACY STAFF including trainees	POSITION		
1			
2			
3			
4			

1. Schedule II Medications Audit

- Choose specific CII medications for audit
- Compare to product movement report for two weeks prior to visit

	Medication 1	Medication 2	Comment/Observation
Drug Name			
Perpetual Inventory Quantity			
Actual Quantity on Hand			
Orders logged in perpetual inventory in accordance with 247 CMR 9.01(14)?			
Prescriptions logged in perpetual inventory in accordance with 247 CMR 9.01(14)??			
Returns/Reverse distribution logged in perpetual inventory in accordance with 247 CMR 9.01(14)??			
Perpetual Inventory reconciled at least every 10 days in accordance with 247 CMR 9.01(14)?			

2. Schedule CIII-CV Medications Audit

- Choose specific CIII-CV medications for audit

	Medication 1	Medication 2	Comment/Observation
Drug Name			
Expected Quantity on Hand			
Actual Quantity on Hand			

Item No.	CII Recordkeeping and Security	YES	NO	N/A	Comment / Observation
	Perpetual Log				In accordance with 247 CMR 9.01(14)
1	All CII medications are maintained in a perpetual log that is reconciled at least every 10 days? 1. Date of Last Perpetual Inventory: _____				
2	Expired CII medications are maintained in a perpetual log until they are reverse distributed? 1. Reverse Distribution Company? _____ 2. Date Schedule II Medications last returned: _____ 3. Reverse 222 Forms completed?				
	CII Ordering				In accordance with 247 CMR 9.01(1)
3	CII medications are ordered in accordance with 247 CMR 9.01(1) and 21 CFR 1305.12(d)? Specify ordering method (circle one): 1. DEA 222 Forms 2. CSOS				
4	DEA 222 forms/CSOS orders completed in accordance with 247 CMR 9.01(1), and 21 CFR 1305.13(e), and 21 CFR 1305.22(4)(g)?				
5	Who is responsible for ordering CII medications?				
6	Does each individual who orders CII have a Power of Attorney (POA) in accordance with 247 CMR 9.01(1) and 21 CFR 1305.05(a)?				
7	Who is responsible for physically receiving (stocking) ordered CII medications?				
8	Who records received orders into the perpetual log?				
	CII Security				In accordance with 247 CMR 6.02(6)(c)
9	CII medications are stored in accordance with 247 CMR 6.02(6)(c)? Specify storage method (circle one): 1. Secured within a locked cabinet/ safe/ other: _____ 2. Dispersed throughout the stock of CVI Medications				
10	Expired / Damaged / Recalled CII medications stored in accordance with 247 CMR 6.02(6)(c)? (describe storage)				
11	Who is authorized to handle CII medications and what are they authorized to do?				

Item No.	Schedule CIII - CV Recordkeeping and Security	YES	NO	N/A	Comment / Observation
	Schedule CIII-CV Ordering				In accordance with 247 CMR 9.01(1)
12	CIII - CV invoices or packing slips stored in accordance with 247 CMR 9.01(1) and 21 CFR 1304.21(d)?				
13	CIII - CV invoices or packing slips completed in accordance with 247 CMR 9.01(1) and 21 CFR 1304.21(d)?				
14	Who is responsible for ordering CIII - CV medications?				
15	Who is responsible for physically receiving (stocking) ordered CII I- CV medications?				
	Schedule CIII - CV Security				In accordance with 247 CMR 6.02(6)(c)
16	CIII - CV medications are stored in accordance with 247 CMR 6.02(6)(c)? Specify storage method (circle one): 1. Secured within a locked cabinet/ safe/ other: _____ 2. Dispersed throughout the stock of CVI Medications				
17	Expired / Damaged / Recalled CII I- CV medications stored in accordance with 247 CMR 6.02(6)(c)? (describe storage) 1. Reverse Distribution Company? _____ 2. Date CIII - CV Medications last returned: _____ 3. Reverse Distribution Forms completed?				
18	Who is authorized to handle CIII - CV medications and what are they authorized to do?				
	Biennial Inventory				In accordance with 247 CMR 6.07(1)(i)
19	Last Biennial Inventory Completed in accordance with 247 CMR 6.07(1)(i)? 1. Date of last Biennial Inventory: _____				
20	Exact counts of CII medications in accordance with 21 CFR 1304.11(3)(6)(i)?				
21	How were CIII - CV medications Counted? Specify count method (circle one): 1. Exact Count 2. Estimated Count				(Note: if the container holds more than 1,000 tablets or capsules, an exact count of the contents is required.)

Item No.	Pharmacy Security	YES	NO	N/A	Comment / Observation
22	Does the pharmacy have policies and procedures regarding who has access to pharmacy area? 1. Who has access to pharmacy keys / alarm codes?				
23	Does the pharmacy have security cameras? 1. Number of cameras: _____ 2. Prescription areas covered? 3. How long is security footage kept? _____ 4. How often is footage reviewed and who reviews security footage?				
24	Is the pharmacy department secured (doors closed and secure, only accessed by pharmacy employees, pharmacy keys secure, etc.) in accordance with 247 CMR 6.02(6)?				
25	Is the medication safe / cabinet locked and secured in accordance with 247 CMR 6.02(6)(c)? 1. Who has access to the safe / cabinet? 2. Who is responsible for the security / maintenance / accessibility of the safe / cabinet?				
26	Are employees allowed to bring personal items (bags, backpacks, coats, jackets, etc.) into the prescription processing or storage area?				

Investigator Notes:

Exit Interview:

I have participated in the controlled substance management review and have reviewed the report with the investigator(s). I understand that this review includes some regulatory requirements, as well as best practice recommendations. [1]

Print Name: _____ License Number: _____

Signature: _____ Title: _____

Investigator Signatures:

Investigator: _____

Date: _____

Investigator: _____

Date: _____

[1] Controlled Substance Management Review line items without a regulatory citation should be considered a best practice recommendation or discussion point.